

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



FZ

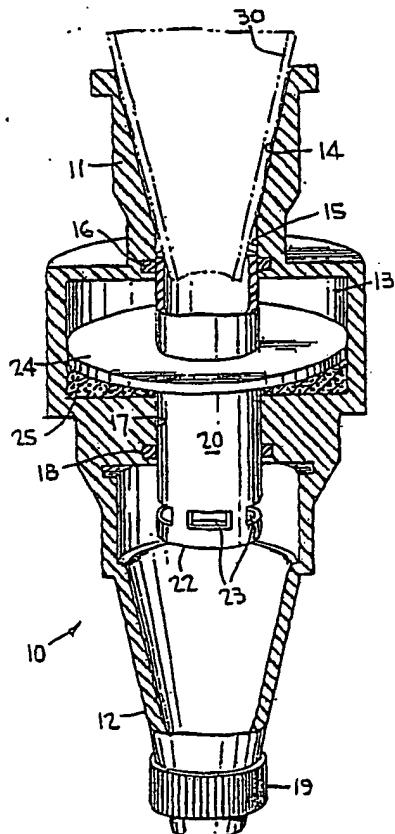
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ³ : A61M 5/00	A1	(11) International Publication Number: WO 83/ 02559 (43) International Publication Date: 4 August 1983 (04.08.83)
(21) International Application Number: PCT/US82/00137	Published <i>With international search report.</i>	
(22) International Filing Date: 28 January 1982 (28.01.82)		
(71) Applicant: WHITMAN MEDICAL CORPORATION [US/US]; 990 Raritan Road, Clark, NJ 07066 (US).		
(72) Inventors: GORDON, Marvin ; 27 Lynnfield Drive, East Windsor, NJ 08520 (US). LICHTENSTEIN, Joseph ; 101 Devon Road, Colonia, NJ 07067 (US).		
(74) Agents: HOLMAN, John, Clarke et al.; Holman & Stern, 2401 Fifteenth Street, N.W., Washington, DC 20009 (US).		
(81) Designated States: AT (European patent), AU, BE (European patent), BR, CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), JP, LU (European patent), MC, NL (European patent), NO, RO, SE (European patent).		

(54) Title: SAFETY VALVE FOR PREVENTING AIR EMBOLISM OR HEMORRHAGE

(57) Abstract

A safety valve (10) for catheterization procedures is characterized by a piston (20) having an internal flow path, a portion of the piston (20) being surrounded by an elastomeric member (25) which surrounds a portion of the piston (20) and biases it to a closed position. The elastomeric member (25) also severely restricts fluid flow around the piston (20) to eliminate any flow path other than the internal piston (20) flow path.



SAFETY VALVE FOR PREVENTING AIR EMBOLISM OR HEMORRHAGE

TECHNICAL FIELD

The present invention relates to a valving apparatus and method employed in a catheter arrangement to prevent entry of air into a patient's circulatory system and to prevent uncontrolled hemorrhaging.

BACKGROUND OF THE INVENTION

During various medical catheterization procedures, such as cardiac catheterization, central venous catheterization for parenteral nutrition, arterial catheterization, etc., there is a severe danger of a fatal air embolism and/or uncontrolled hemorrhaging. Such serious consequences can occur during the process of catheter insertion when the syringe is removed in order to thread the catheter, or during tubing changes, or if the intravenous tubing becomes inadvertently detached from the intravenous catheter, or after the catheter has been withdrawn and before the tract seals.

Attempts to prevent inadvertent separation of the tubing have included taping the components together or physically forcing them into one another; however, these attempts have not solved the problem and, in fact, sometimes result in air leaks by fracturing the hubs. In addition, certain safety valve arrangements have been attempted, such as those described in U.S. Patents Nos.

- 2 -

2,693,801 (Foreman); 3,105,511 (Murphy); 3,399,677 (Gould, et al.); and 3,570,484 (Steer, et al.). In each of these devices the mechanism which actuates valve closure to provide the safety feature is disposed in
5 the flow path of the administered fluid. Any tendency of the fluid to agglomerate on the mechanism comprises the safety feature. Moreover, such valves as disclosed in the aforementioned references, tend to be sufficiently complex and expensive as to render them less than
10 ideal for disposability after use in a single procedure, lack of disposability, on the other hand, requires that the valve be cleaned and resterilized before each use. Further, it is questionable as to whether or not the valves in the aforementioned patents are sufficiently
15 fast-operating to preclude a sudden explosive burst of air from entering the patient's vascular system during the valve closure interval.

SUMMARY OF THE INVENTION

It is a primary object of the present invention
20 to provide a safety valve which is readily inserted in a central venous catheterization line (such as would be used for parenteral nutrition) and which precludes occurrence of an air embolism while the valve is closing as well as after the valve is closed. It is a further
25 object of the present invention to provide such a safety valve for use in any vascular injection arrangement and which prevents air embolism and/or hemorrhage. It is another object of the present invention to provide a valve of the type described which is inexpensive
30 and simple to manufacture, yet reliable in operation.

SUBSTITUTE SHEET



- 3 -

In accordance with the present invention, the bias force for effecting closure in a safety valve is provided by an elastomeric material which also serves the function of diffusing or blocking sudden fluid flow through the valve chamber around the normal valving mechanism. The valve includes a piston arranged to reciprocate longitudinally in the valve chamber while opposite ends of the piston project into inlet and outlet openings of the chamber. A flange, in the form of a flat disc, surrounds the piston and extends radially therefrom in the chamber. The elastomeric material likewise surrounds the piston and fills the valve chamber on one side on the flange, the material being arranged to bias the piston toward the inlet end of the chamber. The piston is hollow and has an open inlet end, a closed outlet end, and outlet slots defined through the cylindrical wall of the piston proximate the outlet end. When biased fully toward the inlet end, the piston is disposed such that the outlet slots are blocked with respect to the valve outlet. In use, a male adaptor of a catheter tube is forced into the valve inlet end where it is held by frictional engagement. In this position, the tube adaptor is inserted into the open end of the piston and pushes the piston toward the outlet end of the valve chamber against the opposing force of the elastomeric material which is thereby compressed. This pushes the piston outlet slots to a position wherein they are no longer blocked and permits fluid to pass through the valve from the catheter tube via the piston interior. Should the adaptor become dislodged from its friction fit, the resilience of the elastomeric material acts on the flange to force the piston back toward the inlet end of the chamber into a position wherein the outlet slots are blocked. Importantly, the elastomeric material is a of a type which

SUBSTITUTE SHEET



- 4 -

blocks or severely restricts flow of fluids therethrough so that sudden air flow into the patient's vascular system by air trapped in the chamber around the outside of the piston is prevented.

5

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood by referring to the accompanying drawings, wherein:

Figure 1 is a plan view in section of a preferred embodiment of the present invention illustrating the valve in a closed position; and

Figure 2 is a view similar to that of Figure 1, but illustrating the valve in an open position.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring more specifically to the drawings, the 15 valve 10 of the present invention includes an inlet section 11 and an outlet section 12 separated by a valve chamber 13. Inlet section 11 includes a generally conical portion 14 which tapers or narrows towards valve chamber 13. Conical portion 14 terminates in an 20 annular wall 15 which defines an inlet opening to valve chamber 13. An O-ring 16 or the like is disposed in a suitably provided annular notch in wall 15. Inlet section 11 is arranged to receive and frictionally engage a male adaptor 30 of a catheter tube in a tight fit 25 engagement.

Outlet section 12 includes an annular wall 17 which defines the outlet opening from chamber 13. An

BEST AVAILABLE COPY SUBSTITUTE SHEET

BUREAU
OMPI

- 5 -

O-ring or the like is disposed within a suitably provided annular notch in wall 17. The portion of outlet section 12 downstream of wall 17 tapers in a generally conical manner to a diameter suitable for connection 5 to a catheter tube by means of Luer lock 19 or the like.

Valve chamber 13 is generally cylindrical in the illustrated embodiment, but this configuration is by no means a limiting factor of the invention. The chamber inlet opening, defined by wall 15, and the chamber outlet opening, defined by wall 17, are generally aligned and sized to permit a piston 20 to slide longitudinally therethrough. Piston 20 has an open inlet end 21 and a closed outlet end 22. A plurality of outlet slots 23 are defined through the piston wall proximate outlet end 22 so as to define a flow path from open inlet end 21 through the piston interior, and out through slots 23. The outer periphery of piston 20 is sized to provide a pressure seal contact with each of O-ring 16, 18 while permitting the piston to freely slide within those O-rings. A disc-like flange 24, preferably formed integrally with the piston, surrounds the piston and extends radially therefrom in the valve chamber 13. Disc 24 is larger than either the inlet opening 15 or outlet opening 17 of the valve chamber and thereby 25 retains the piston in the chamber.

The region of valve chamber 13 between disc 24 and outlet opening 17 is filled with an elastomeric material 25 which surrounds piston 24. Material 25, in the embodiment shown, is generally doughnut-shaped so as 30 to entirely fill the valve chamber portion below flange 24. Of course, if chamber 13 is not cylindrical, the shape of material 25 should be changed accordingly. Material 25 is sufficiently resilient to exert sufficient force on flange 24 to bias the piston and flange

- 6 -

toward chamber inlet 15 to the position illustrated in Fig. 1. This is defined as the closed position of the valve. It is noted that, in this position, the flange 24 abuts the inlet end of the valve chamber 13 while 5 inlet end 21 of the piston 20 projects through inlet opening 15 into region 14. The outlet end 22 is disposed such that outlet slots 23 are blocked from communication with outlet section 12 by outlet wall 17 and O-ring 18. Material 25 must be able to perform this 10 biasing function while serving to block, or at least severely restrict, the flow of liquids and gases through the chamber, even in the closed position of the valve (Fig. 1) wherein the material is expanded. Elastomeric materials of this nature are quite well known, examples 15 of such comprising cellular or non-cellular material or synthetic rubbers or plastics, such as highly dense or closed cellular polyurethane, styrene butadienes, isoprenes, and the like.

In use, as illustrated in Figure 2, the adaptor 20 30 of a catheter tubing is inserted into inlet section 11 until firmly wedged or friction engaged in conical portion 14. In this position the tip of the adaptor is inserted into inlet opening 21 of piston 20 and forces the piston into chamber 13 against the biasing 25 action of resilient material 25. Specifically, flange 24 compresses material 25 as it is urged into chamber 13 by the frictionally engaged adaptor 30. In this position, outlet slots 23 extend beyond chamber outlet 17 and into valve outlet section 12 so that fluid being 30 administered can flow from adaptor 30 through piston 20 and out through outlet section 12 to the attached catheter tube. This is the open position of the valve. If the adaptor should become dislodged, either accidentally or intentionally during a tubing change, the 35 adaptor 30 will no longer push the piston against the

SUBSTITUTE SHEET

BUREAU
OMPI

- 7 -

bias force of material 25. This material therefore returns the piston to the closed position of Figure 1 wherein outlet slots 23 are blocked from communication with outlet section 12 of the valve.

5 It should be noted that in any valve position, material 25 precludes the existence of a flow path between chamber inlet 15 and chamber outlet 17 around the outside of the piston. That is, material 25, being closed cell or very dense open cell material, blocks
10 or severely restricts fluid flow through the chamber position it fills. Thus, if the adaptor 30 is dislodged, an initial inrush of air through the main valve flow path (i.e. through piston 20) is precluded while the valve is closing because of the supply fluid remaining
15 therein immediately after the adaptor 30 is removed. In addition, the resilient material precludes air trapped in the valve from flowing around the piston to the outlet section. Thus, the valve positively precludes air embolism. Likewise, the valve precludes uncontrolled
20 hemorrhaging by virtue of the same main valve path safety closure and the blockage or restriction provided by material 25. Thus, not only is the valve useful for central venous catheterization to provide parenteral nutrition, but it is also useful as a diagnostic gate
25 to permit multiple blood withdrawals from an artery or vein without fear of uncontrolled hemorrhaging.

It is noted that the valve as described, has no obstructions in the main valve path which would collect residual blood clotting or block intravenous fluid.

30 The size of disc-like flange 24 should be as large as possible to provide as large a possible surface over which the bias force of material 25 can act. In addition, flange 24 should be as thin as possible without sacrificing rigidity, so that the mass of the piston

- 8 -

and flange is minimized whereby the speed of valve response is maximized. Of course, the limitation of flange size is the contour of chamber 13; that is, the edges of flange 24 should not contact the chamber wall
5 because the resulting drag would slow valve response.

O-rings 16, 18 may be dispensed with if the material used for piston 20 and walls 15, 17, and the sizes of the piston and these walls are selected to provide the necessary fluid sealing while permitting
10 sufficient freedom for the piston to slide in these walls. In this regard, Teflon may be a suitable material for walls 15 and 17.

The instant invention is not to be limited to the exact details of constructions shown and described,
15 for obvious modifications can be made a person skilled in the art.

SUBSTITUTE SHEET

BUREAU
OMPI

- 9 -

I CLAIM:

1. An improvement in safety valves of the type used in catheterization procedures wherein a valve chamber includes a piston which is reciprocable between two positions in said chamber by means of a resilient bias member which urges the piston to a first of said two positions in which the valve is closed and by means of a connection to a fluid conduit which urges said piston to a second of said two positions wherein said valve is open, said improvement comprising:

an internal flow path in said piston including means responsive to said piston being in said second position for freely conducting flow through said piston;

means for blocking flow through said internal flow path when said piston is in said first position;

and wherein said bias member comprises elastomeric flow restrictive means surrounding a portion of said piston in said chamber for at least severely restricting flow through said chamber around said piston.

2. The valve according to Claim 1, wherein said elastomeric flow restrictive means is made of rubber.

3. The valve according to Claim 1, wherein said elastomeric flow restrictive means is made of highly dense plastic material.

SUBSTITUTE SHEET



- 10 -

4. The valve according to Claims 1, 2 or 3, wherein said connection to a fluid conduit comprises a generally conical receiving section for frictionally engaging an end of a catheter tube.

5. A safety valve for use in administering fluid into and withdrawing fluid from a patient, said valve comprising:

a valve chamber having first and second openings;

a valve member positioned in said chamber, said valve member having first and second ends projecting through and slidably within said first and second openings, respectively, said valve member having an inlet opening at said first end, an outlet opening proximate said second end and an internal flow path between said inlet and outlet openings;

retainer means projecting transversely from said valve member in said chamber for preventing removal of said valve member from said first and second openings while defining first and second extreme positions of said valve member in said chamber, said retainer means defining a sub-chamber in said valve chamber which sub-chamber is disposed between said retainer means and said second opening and changes in volume as the valve member slides;

closure means for preventing fluid flow through said outlet opening when said valve member is in said first position and permitting such flow when said valve member is in said second position;

bias means disposed in said valve chamber for biasing said valve member to said first position, said bias means comprising a resilient elastomeric member

SUBSTITUTE SHEET

BUREAU
OMNI

- 11 -

located between said retainer means and said second opening and comprised of a material which is at least severely restrictive to flow therethrough when in a relaxed state; and

a valve inlet section including means for engaging a flow tube with the flow tube in communication with said inlet opening while forcing said valve member to said second position.

6. The valve according to Claim 5, wherein said chamber is substantially cylindrical, wherein said valve member is a generally cylindrical piston, wherein said retainer means is an annular disc surrounding and projecting radially from said piston, and wherein said resilient member is a generally doughnut-shaped member.

7. The valve according to Claim 6, wherein said resilient member is made of rubber.

8. The valve according to Claim 6, wherein said valve member is made of plastic.

9. A safety valve for use in catheterization procedures comprising:

a valve chamber having first and second openings;

a movable member disposed in said chamber;

means for constraining said movable member to move between first and second positions in said chamber;

a flow passage defined internally of said movable member and having inlet and egress openings;

SUBSTITUTE SHEET

BUREAU
OMPI

- 12 -

means for constraining said inlet opening into permanent flow communication with said first chamber opening for all positions of said movable member;

means responsive to insertion of a fluid conduit into said first chamber opening for forcing said movable member to said second position;

means for blocking flow through said egress opening in said position of said movable member;

means for conducting flow from said egress opening out through said second chamber in said second position of said movable member; and

bias means for continuously moving said movable member toward said first position, said bias means comprising an elastomeric member made of material which is at least severely restrictive to flow therethrough, said elastomeric member being disposed in said chamber to surround said movable member.

10. The safety valve according to Claim 9, wherein said bias means further comprises a flange projecting from said movable member to sub-divide said chamber into first and second compartments which vary in volume with positional changes of the movable member in the chamber, said first compartment communicating directly with said second chamber opening, and wherein said elastomeric member entirely fills the volume of said second compartment surrounding said movable member.

SUBSTITUTE SHEET



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US82/00137

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all):

According to International Patent Classification (IPC) or to both National Classification and IPC

INT CL3 A61M 5/00
US CL 128/214R

II. FIELDS SEARCHED

Minimum Documentation Searched⁴

Classification System	Classification Symbols
US	128/214, 274, 348, 349B, 349BV 251/149.6, 339, 347 141/291, 296 137/399, 878

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched⁵III. DOCUMENTS CONSIDERED TO BE RELEVANT¹⁴

Category ¹⁵	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
X	US,A, 3,087,492, Published 30 April 1963 Garth	1-10
X	US,A, 3,399,677, Published 03 September 1968 Gould et al	1-10
X	US,A, 3,570,484, Published 16 March 1971, Steer et al	1-10
A	US,A, 2,693,801, Published 09 November 1954 Foreman	1-10
A	US,A, 3,105,511, Published 01 October 1963 Murphy, Jr.	1-10
A	US,A, 3,538,950, Published 10 November 1970, Porteners	1-10
A	US,A, 3,923,065, Published 02 December 1975 Nozick et al	1-10
A	US,A, 3,965,910, Published 29 June 1976 Fischer	1-10

¹⁵ Special categories of cited documents:¹⁹

"A" document defining the general state of the art

"E" earlier document but published on or after the international filing date

"L" document cited for special reason other than those referred to in the other categories

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the International filing date but on or after the priority date claimed

"T" later document published on or after the International filing date or priority date and not in conflict with the application, but cited to understand the principle or theory underlying the invention

"X" document of particular relevance

IV. CERTIFICATION

Date of the Actual Completion of the International Search²⁰

31 March 1982

Date of Mailing of this International Search Report²¹

22 APR 1982

International Searching Authority²²

ISA/US

Signature of Authorized Officer²³

STEPHEN G. FELLEGRI

111.

FIG. 1

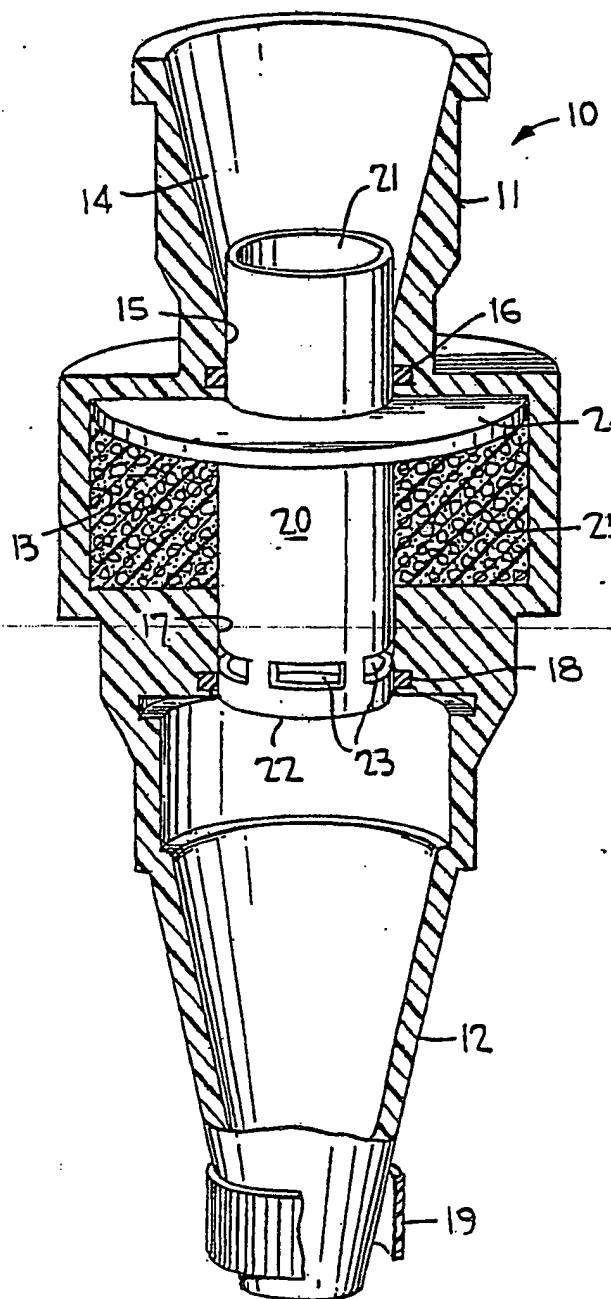


FIG. 2

